Bittium Respiro™

Operating Instructions for healthcare professionals

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Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland
Phone: +358 40 344 2000
www.bittium.com

Notice

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Summary of Changes

Version	Date	Changes Between Releases	Status
2.0	2023.12.11	New layout. Categorized notes and warnings.	Approved

Table of Contents

1 CONVENTIONS

The following conventions are used in these user instructions:

WARNING: Warning statements describe conditions or actions that can result in personal injury or loss of life.

CAUTION: Caution statements describe conditions or actions that can result in damage to the equipment or loss of data. Caution statements alert the user that the clinician has the responsibility of determining significance of results due to actions and varying factors present with each case.

NOTE Notes contain additional information on using this product.

TIP Tips contain additional information on how to make use of the features and functions of the device.

The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Regulation 2017/745.

1.1 Terminology

Table 1 Terms used in the document

Term	Description
ECG	Electrocardiogram
EDF	European Data Format
HSAT	Home sleep apnea testing
IP	Ingress Protection
MDR	Medical Device Regulation

2 GENERAL WARNINGS AND CAUTIONS TO REVIEW BEFORE USE

Do not operate Bittium Respiro™ device without first reviewing the following notices.

WARNING: Do not use a broken device or a RIP belt, ECG adapter, ECG electrode or cannula for which the packing has been opened. Contact nursing staff if the devices and sensors are damaged.

WARNING: Nasal cannula, ECG adapter, ECG electrodes and RIP belts are for single-use only. Reuse between patients is strictly prohibited. The reuse of single-use parts may lead to contamination.

WARNING: RIP belts must not be worn against skin.

WARNING: Respiro is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.

WARNING: Position the nasal cannula carefully. Use medical tape for securing the cannula. Make sure that the cannula length is optimal for each patient. Avoid using too long cannulas to ensure patient safety.

WARNING: Do not open and/or modify the equipment.

CAUTION: Use only the included charger and the charging dock when charging Respiro™.

CAUTION: Respiro device's internal pressure sensor is very sensitive. Do not produce excessive pressure to nasal cannula's pressure hose.

CAUTION: Use only mild detergents when cleaning the devices. Immersing the devices in liquids is prohibited.

CAUTION: Nail polish and artificial nails must be removed before recording as they interfere with the pulse oximeter.

CAUTION: Do not use the devices in shower or sauna. IP67.

CAUTION: EMC disturbances may cause interference and/or noise to recording data.

CAUTION: Respiro device should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

CAUTION: Use the device only with accessories provided by Bittium Biosignals Ltd. Other accessories may negatively affect the device performance or cause non-recognized issues and non-conformities or break the device.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Respiro device, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result. Examples of such devices include: mobile phone, laptop computer, activity band, smart ring.

CAUTION: Before operating Respiro device, please read this manual thoroughly and keep it for future reference. Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

CAUTION: You must ensure that the operating system in the computer you are using is up-to-date and secure

CAUTION: Respiro is not suitable for use in MRI environment.

NOTE	The connector for the pulse oximeter is a push-pull connector. Do not twist or bend the connector when connecting the pulse oximeter sensor.
NOTE	Do not use excessive force when connecting the nasal cannula
NOTE	Keep the devices and accessories out of reach for children and pets.
NOTE	Body and hand creams as well as sunscreens can damage the device
NOTE	Skin must be intact, clean, and dry in the area where the ECG electrode is attached (applicable only in ECG use case).
NOTE	Body-worn parts (eg. medical tape) may irritate skin, but there are no other known adverse events due to using the Respiro device. If the patient has lots of body hair it must be shaved from the area where the ECG electrode is attached (applicable only in ECG use case).
NOTE	Any serious incident that has occurred in relation to the device must be re-ported to the manufacturer and the competent authority of the country in which the user and/or patient is established.
NOTE	We recommend changing the batteries of the Nonin 3150BLE pulse oximeter after each recording night or at the latest every two recording nights to ensure that the pulse oximeter's battery capacity is sufficient for the entire recording period.
NOTE	The screenshots shown in the document may not represent the latest software User Interface views.

3 INTRODUCTION

These instructions cover the correct and safe use of the Respiro™ sleep apnea device. Respiro provides reliable recordings of selected sleep apnea-related bio signals in home sleep apnea testing (HSAT).

CAUTION: Before operating Respiro device, please read this manual thoroughly and keep it for future reference. Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

3.1 Respiro intended use

The device is intended to be used as an ambulatory recording device for overnight polygraphy, which is always carried out by doctor's prescription. Use of Respiro for any other purpose is prohibited. Respiro is used either in a hospital or at patient's home. The device records patient's bio signals. The device does not actively monitor the patient's status, diagnose, or treat the patient and it cannot be used as a life-sustaining device. The device is not designed to be used with children. The device is operated by healthcare professionals at hospital, the patient, or another person at the patient's home. A healthcare professional always gives instructions to the patient or the device operator on using the device and starting the recording before use at home. The patient is provided with an illustrated quick guide for home use.

Image below gives an overview of the device and its interfaces.

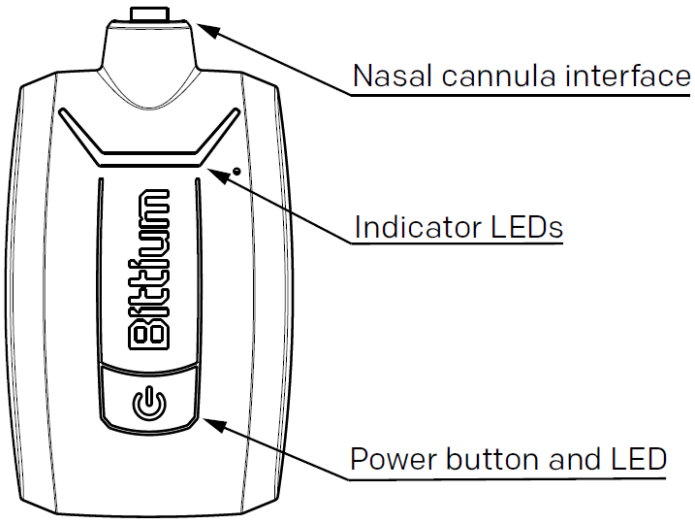


Figure 1 Respiro device interfaces

Figure below presents the pulse oximeter and the sensor.

Figure 2 Pulse oximeter and sensor

See also pulse oximeter's operator's manual: Operator's Manual Model 3150 WristOx2® Pulse Oximeter BLE and USB: https://www.nonin.com/support/3150-ble/. Operator's Manual can also be found from device's memory.

NOTE The screenshots shown in the document may not represent the latest software User Interface views.

3.2 Adverse events

Body-worn parts (eg. medical tape) may irritate skin, but there are no other known adverse events due to using the Respiro device.

3.3 Indications

- Suspected sleep-related breathing disorder (obstructive sleep apnea, central sleep apnea, mixed sleep apnea, Cheyne-Stokes breathing)

Table below lists the biosignals and sensors used in Bittium Respiro:

Signal	Sensor
Airflow	Nasal cannula and air pressure sensor
Respiratory effort (abdominal)	Respiratory inductance plethysmography (RIP) belt (abdominal)
Respiratory effort (thorax)	Respiratory inductance plethysmography (RIP) belt (thorax)
Oxygen saturation & pulse rate	Wrist-worn pulse oximeter
ECG monitoring	1-channel ECG electrode
Body position	Integrated accelerometer
Snoring	Integrated microphone for audio volume

3.4 Contraindications

- The product is not intended for pediatric patients. Age limit 18 years.
- Outstandingly big physical size. Sensor adjustment out of control.
- Amputation – missing fingers / both hands (SpO2 measurement not possible).
- Unfeasible to use sensors for any reason (sensitive skin).
- Artificial nails / thick fingernail painting prevents SpO2 measurement.
- Acute respiratory infection, which might be a confusing factor in symptoms and interpretation.
- A person who is unable to perform self-directed / independent recordings at home.

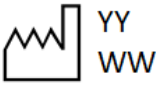
A doctor always assesses the requirement for a night polygraphy and whether the patient is suitable for home recording. Only an expert can interpret and analyze the results of night polygraphy recording and be responsible for the given statements and care.

3.5 Security

System applications are recommended to be used with computers with proper anti-virus protection installed. Use of firewall is also recommended. With any concern related to security please contact medical.support@bittium.com for additional recommendation and support.

3.6 Symbols and Labels

Symbol	Description
	The device complies with the requirements of the Medical Device Regulation 2017/745.
	Type BF applied part (electrically isolated).
	Do not reuse.
	Consult Instruction for use.
	The Lot number.
	For EU only: This symbol indicates that this device shall be dis-posed according to European Union directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
	During transportation: keep package dry, protect from rain.
	Medical device.
IP67	Device is dust-protected and protected against the effects of immersion in water between 15 cm and 1 m for 30 minutes.
IP31	Device is protected against small objects (≥2,5 mm) and condensation.
	Wireless Transmission Symbol.
	A relative humidity range of 10 % to 90 %, non-condensing.
	Transport and storage conditions +10 °C to + 30 °C (transport) +10 °C to + 30 °C at a relative humidity up to 90 %, non-condensing (storage).

REF	Product number. Indicates the catalogue number so that the medical device can be identified.
	Manufacturer.
	Data matrix (GS1) is a two-dimensional barcode consisting of black and white modules arranged in either a square or rectangular pattern, also known as a matrix. The data to be encoded can be text or numeric data. GS1 data matrix includes GTIN and production identifier (PI). • GTIN (01) • Serial number (21) • Date of manufacture (11) • LOT (10)
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed. An atmospheric pressure range of 700 hPa to 1 060 hPa.
	Use-by date.
	Date of manufacture.
	Keep away from sunlight.
	Single patient multiple use.
	Serial number

3.7 User responsibility and warranty

This product shall be assembled, operated, maintained, and repaired in accordance with the instructions provided.

A defective product must not be used. Parts that are broken, worn, missing, incomplete, distorted or contaminated must be replaced immediately. Should any repair or replacement become necessary, we recommend that the device is delivered to your local distributor or Bittium Biosignals Ltd for service.

The user of the product is solely responsible for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Bittium Biosignals Ltd or their authorized service personnel.

The device has been tested to work with the following cannulas:

- SleepSense® 2-Ft Adult Nasal + Oral Pressure Monitoring Cannula
- Pro-Tech Pro-Flow Nasal Cannula, Adult, 16”, VIASYS®
- Pro-Tech Pro-Flow Nasal Oral Cannula, Adult, 8.25” (20.96 cm)

The use of accessories other than those approved by the manufacturer may break the device, decrease its performance, or cause other issues.

Shelf life of the accessories shipped with Respiro can be seen from the product packing markings.

Warranty: 12 months for Respiro and pulse oximeter. Service interval is max. 2 years.

3.8 Device disposal

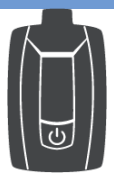
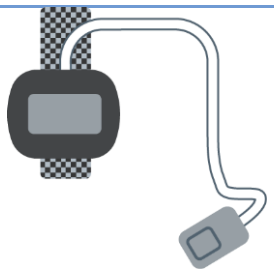
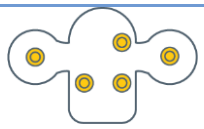
If the product or its documentation bears this mark, it must not be disposed of with other household waste at the end of its life. The device contains electronics that require it to be recycled in an appropriate manner. Take care of the environment and dispose of the device according to the disposal instructions. You can check the location of the nearest recycling point with your local waste disposal authority.

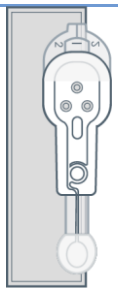
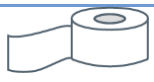
4 USING RESPIRO

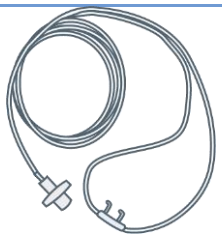
4.1 Respiro Carry case contents

Table below lists the carry case contents as illustrations.

Table 2 Carry case contents

Item	Image
Bittium Respiro™ device (applied part)	
Charger dock	
Medical Power Supply 7W USB (same charger is used with the charger dock)	
Pulse oximeter Nonin 3150 with batteries (type AAA), 2 pcs (inserted)	
RIP (Respiratory inductance plethysmography) belt(s) for attaching Respiro to body (applied part). Two sizes are available, M and L. • Size M: length 80 cm, chest circumference max. 160 cm. Default size. • Size L: length 120 cm, chest circumference 150 - 240 cm	
Respiro patch for 1 RIP belt (Applied part), 2 pcs	

Respiro patch for 2 RIP belts (Applied part), 2 pcs	
Respiro ECG Adapter (applied part, single use)	
Bittium OmegaSnap™ ECG electrode (applied part, single use)	
Bittium Respiro Quick Guide	
Bittium Respiro Notes and Warnings	
Medical tape (applied part, single use)	

Cannula (applied part, single use), (eg. Pro-Tech or SleepSense®).	

WARNING: Do not use a broken device or a RIP belt, ECG adapter, ECG electrode or cannula for which the packing has been opened.

WARNING: Position the nasal cannula carefully. Use medical tape for securing the cannula. Make sure that the cannula length is optimal for each patient. Avoid using too long cannulas to ensure patient safety.

4.2 Carry case packing

Figure below shows the Respiro carry case contents in HSAT™ recording.

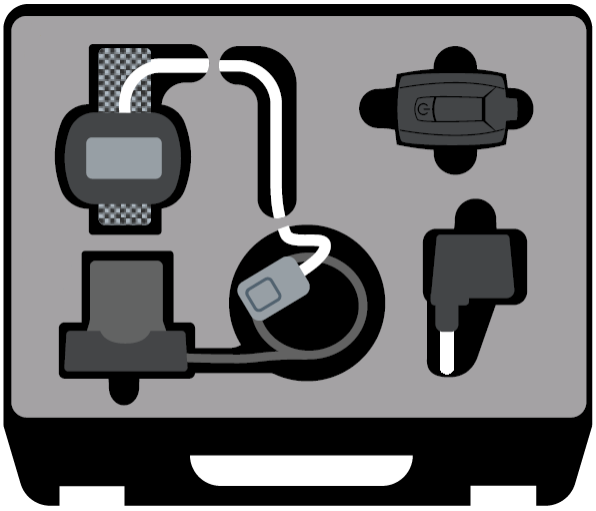


Figure 3 Carry case packing, HSAT

4.3 Configuration options

Respiro polygraphy recording can be carried out as an HSAT™ recording with three configurations:

- 1 RIP belt configuration (abdominal application):

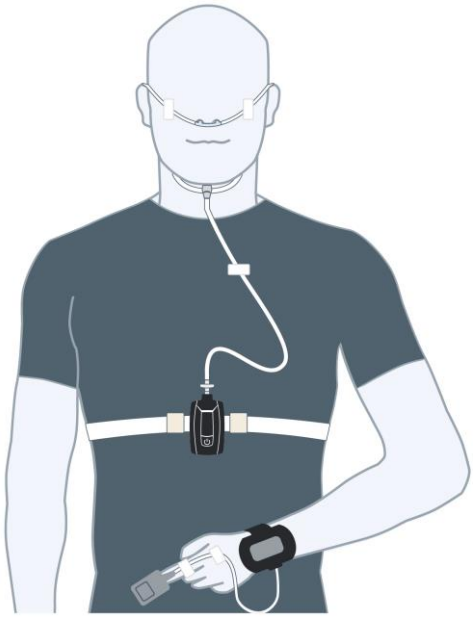


Figure 4 1 RIP belt configuration

- 2 RIP belts configuration (thoracic and abdominal application):

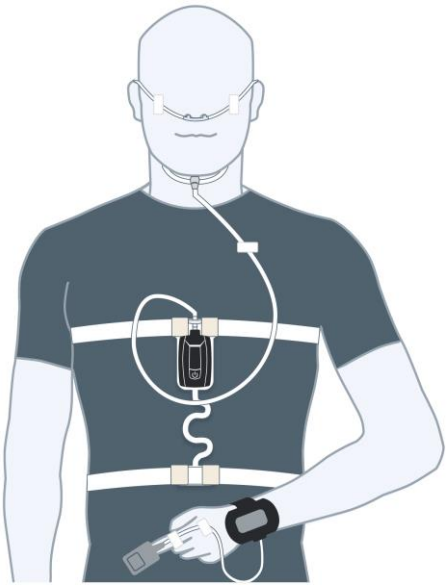


Figure 5 2 RIP belts configuration

- 2 RIP belts configuration with ECG (thoracic and abdominal application with ECG electrode):

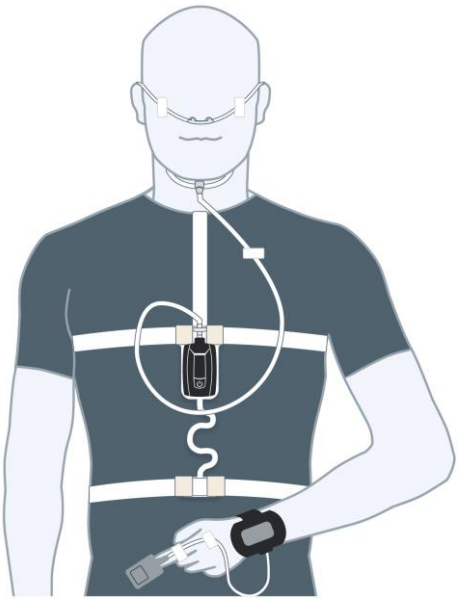


Figure 6 2 RIP belts configuration with ECG

4.4 Equipment needed in recording

See chapter 4.1.

4.5 Respiro indicator LEDs and power button functions

LED indications are shown as viewed from the front of Respiro.

4.5.1 LED indications in idle state

Respiro LED indications in idle state are as shown in the figure below:

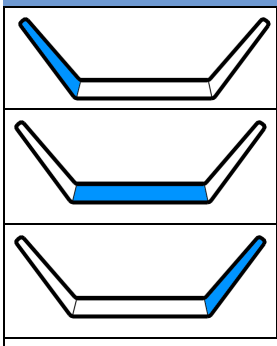
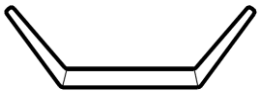
Figure 7 Respiro indicator LEDs in idle state

In this state there is no recording ongoing, and the device is idle. This is the basic state. If no activity occurs in 5 minutes Respiro will shut down. In that state Respiro has no LED indications.

4.5.2 LED indicators during recording

Respiro LED indicators show recording status as described in Table 3 during recording. For potential error situations refer to Chapter 6

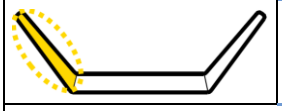
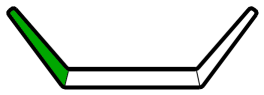
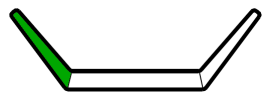
Table 3 LED indicators during recording

Color	Meaning
	Cycling blue lights: Respiro vibrates once, recording start ongoing When recording is ended, Respiro vibrates 3 times and the LEDs flash once.
	Green LEDs on after recording start for 30 seconds: All sensors ok. Indication is same if patient stands up during recording or if patient has first entered a patient marker indication.
	No LEDs on: Respiro in sleep mode, recording ongoing. Patient not standing.
	Middle LED blue for 3 seconds: Patient marker indication when power button is pressed once.

4.5.3 LED indicators while charging Respiro

Respiro LED indicators blink as described in Table 4 when Respiro is charged in its charging dock.

Table 4 LED indicators during recording

Color	Meaning
	Leftmost LED blinking yellow: Battery charge 0-29 %.
	Leftmost LED blinking green: Battery charge 30-49 %.
 	Two leftmost LEDs turn successively green, rightmost LED off: Battery charge 50-89 %.
  	All three LEDs turn successively green: Battery charge 90-94 %.
	All LEDs static green: Battery charge 95-100 %.

4.5.4 Power button functions

Respiro device's power button has the following functions:

- A press of approx. 3 seconds: Respiro power on.
- After power on a press of approx. 8 seconds after which Respiro vibrates once: Recording start.
- A press of approx. 3 seconds during recording: Recording end. Respiro vibrates 3 times.
- Short press (<3 seconds): Patient event marker set indication during recording.
- A press of approx. 12 seconds: Respiro device power off.

See also chapter 4.5.2 for corresponding UI indications.

4.6 Before recording

Make sure that the Respiro device's battery charge status is sufficient (at least two green LEDs are blinking successively according to Table 3 while charging. Note! If scheduled recording is used all three indicator LEDs must be blinking successively to ensure sufficient battery charge for the recording) for the planned recording and that the pulse oximeter's batteries are good and have a sufficient charge. Different types of batteries (alkaline, lithium, rechargeable) can have an effect on the pulse oximeter's operating time. We recommend changing the batteries of the Nonin 3150BLE pulse oximeter after each recording night or at the latest every two re-cording nights to ensure that the pulse oximeter's battery capacity is sufficient for the entire recording period.

When registration is on OR when Respiro is set in the Charger dock, the communication between Respiro and the pulse oximeter is active which also drains the pulse oximeter's batteries. This is why we recommend to change the pulse oximeter batteries only after Respiro has been prepared for the next patient.

Figure 8 Battery charge symbol

Respiro battery life is approx. 20 hours of HSAT recording with the largest configuration and Bluetooth® use. It is recommended that Respiro is always fully charged between patients.

TIP If the recording type is 2 RIP belts configuration with ECG and it is necessary to perform a recording for two nights, the patient must be instructed not to remove the ECG electrode after the first night. The electrode can remain attached also while having a shower, but the electrode's snap connectors must be carefully dried after the shower.

4.6.1 Charging Respiro

Set Respiro in the charging dock while making sure that the charging dock is connected to the charger.

TIP Connect the charging dock to the power supply's USB port only. Do not connect it anywhere else for charging.

TIP If a recording state is accidentally on in Respiro device, it is ended automatically when the Respiro device is set in the charging dock

Respiro device's battery is at least 95 % full when all 3 indicator LEDs are green. See chapter 4.5.3.

4.6.2 Attaching the pulse oximeter's wristband

Attach the pulse oximeter's wristband as shown in the images below.

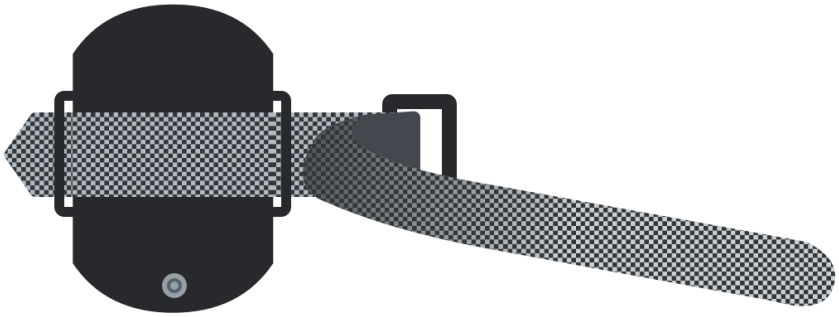


Figure 9 Treading the short part

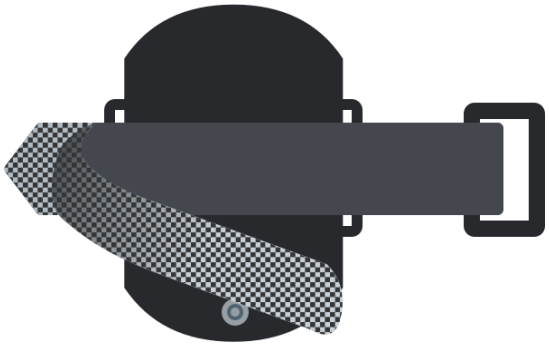


Figure 10 Threading the long part

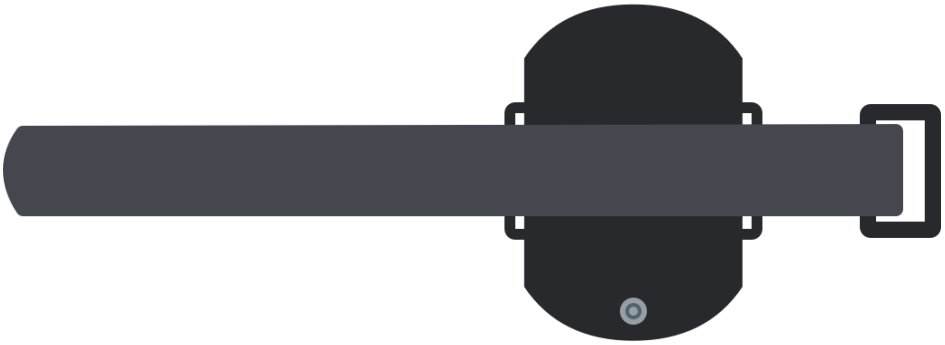


Figure 11 Attached wristband, back view

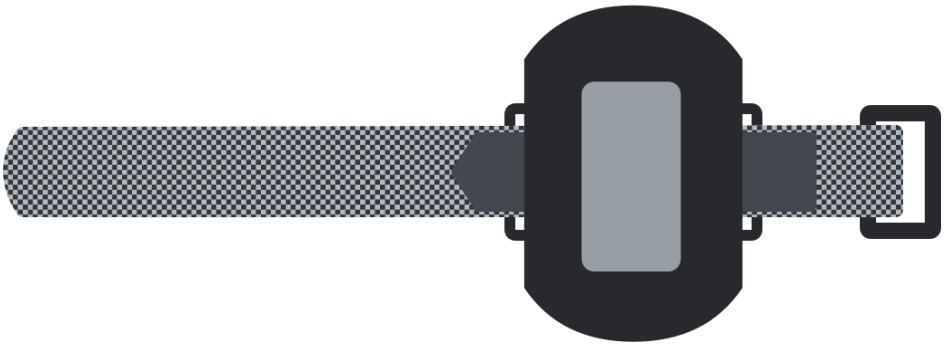


Figure 12 Attached wristband, front view

4.6.3 Checking the device pairs

The carry case equipment (Respiro, pulse oximeter) is already connected together by the manufacturer. Note, however that when for example cleaning several devices at the same time these device pairs may get mixed with other devices. It is possible to find out the device pairs following the instructions below.

TIP Make sure that Respiro is not in the charger dock or connected to a computer when checking the device pairs.

Respiro and pulse oximeter:

1. Start the Respiro devices by pressing the power button approx. 3 seconds. All 3 indicator LEDs are blue.
2. Press the power button again approx. 8 seconds until Respiro vibrates once and all 3 indicator LEDs are blinking blue.
3. Bluetooth connection is formed automatically between Respiro and the pulse oximeter. Press the pulse oximeter's power button with eg. your fingernail to start it if it does not start automatically.

Figure 13 Pulse oximeter power button

4. After Respiro has activated the recording state all 3 indicator LEDs will be blinking blue for few seconds. Then, after the pulse oximeter is started, Respiro device's left LED indicator will be green, if the finger is inserted in the sensor and yellow if it is not. Respiro is not connected to the pulse oximeter in question if the left LED indicator is red.
5. Switch off the Respiro device by pressing the power button. Press the power button for approx. 3 seconds to stop the activated recording state.

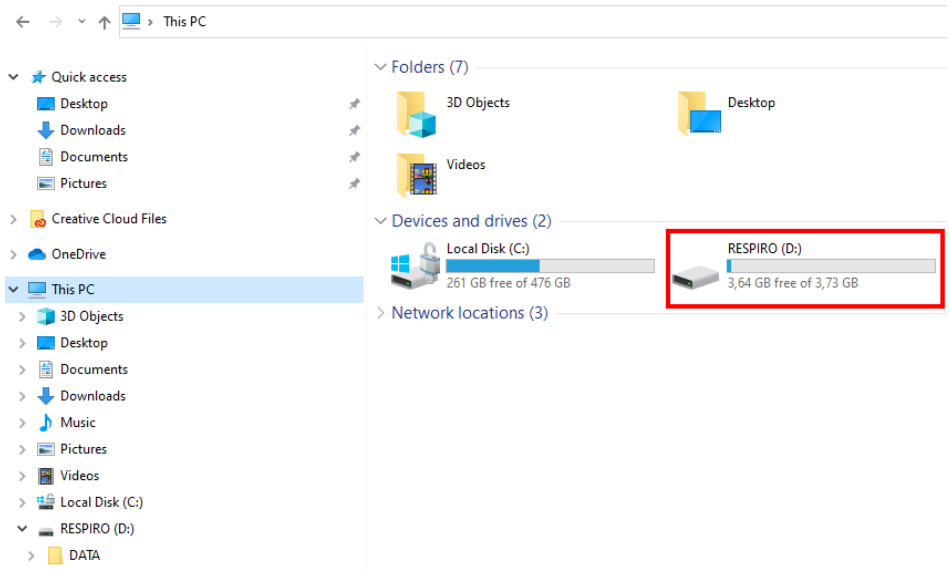
TIP	It is not necessary to switch off the pulse oximeter separately from its power button. It switches off automatically after 10 minutes when there is no Bluetooth connection and when the finger is removed from the sensor

You can also find out the device pairs via Respiro Device Manager by comparing the serial number information in Respiro Device Manager with that shown on the pulse oximeter.

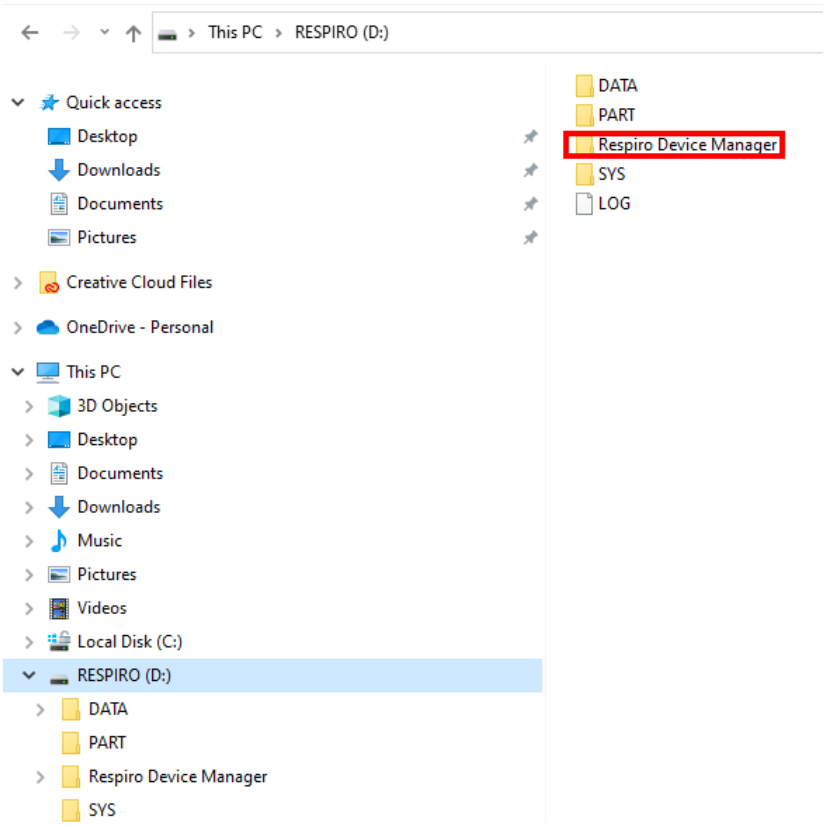
4.6.4 Connecting Respiro and the pulse oximeter

Follow these instructions if you need to connect Respiro and the pulse oximeter again due to eg. a device failure:

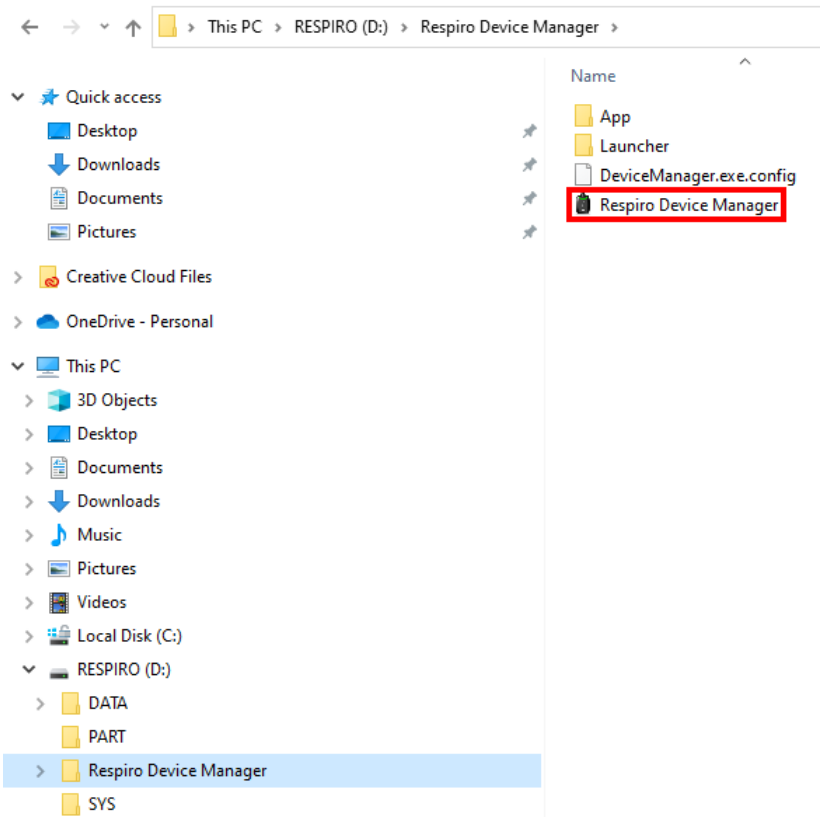
1. Connect the Respiro device's charging dock to a computer with the USB cable.
2. Set Respiro in the charging dock. Respiro indicator LEDs will be blue for a moment until the charging cycle begins and the LEDs blink green cycling from left to right.
3. Start Respiro Device Manager application via Windows File Explorer by double-clicking first the Respiro device icon. You can open the File Explorer by clicking the yellow folder icon at the bottom of the desktop view.
    a) Double-click Respiro device icon.



    b) Double-click Respiro Device Manager folder.

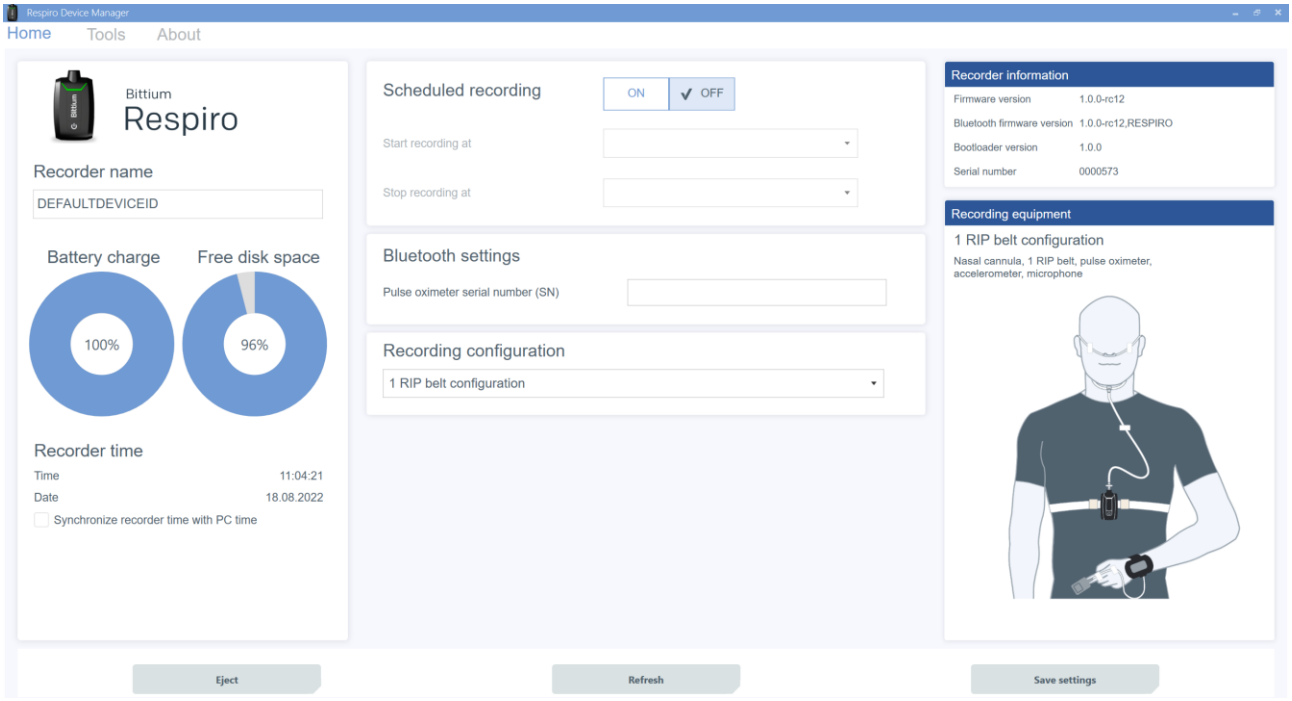


c) Double-click Respiro Device Manager file. A desktop shortcut is created when using Respiro Device Manager for the first time.

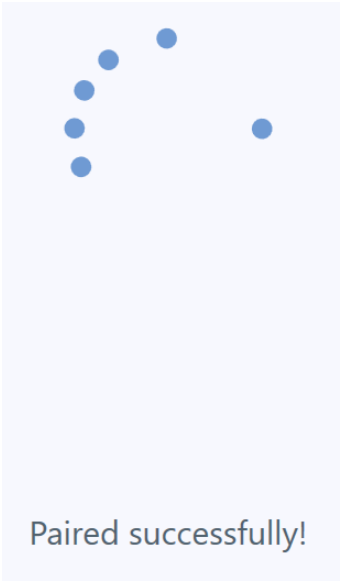


4. Wait for the application to detect Respiro. Make sure that Respiro is inserted in the charger dock and that the charger dock is connected to the computer. Respiro Device Manager main view opens.
5. Enter the pulse oximeter's serial number in the Pulse oximeter device name field in the Respiro Device Manager main view and click Save. If you want to add a name for the Respiro device, you can enter it in the Recorder name field.

TIP Do not use patient information when re-naming Respiro device.



6. Start the pulse oximeter by pressing its power button (see ch. 4.6.3) with eg. your fingernail when the application requests you to do so and click OK. Connecting starts. Alternatively, you can also insert your finger in the sensor and the pulse oximeter starts.



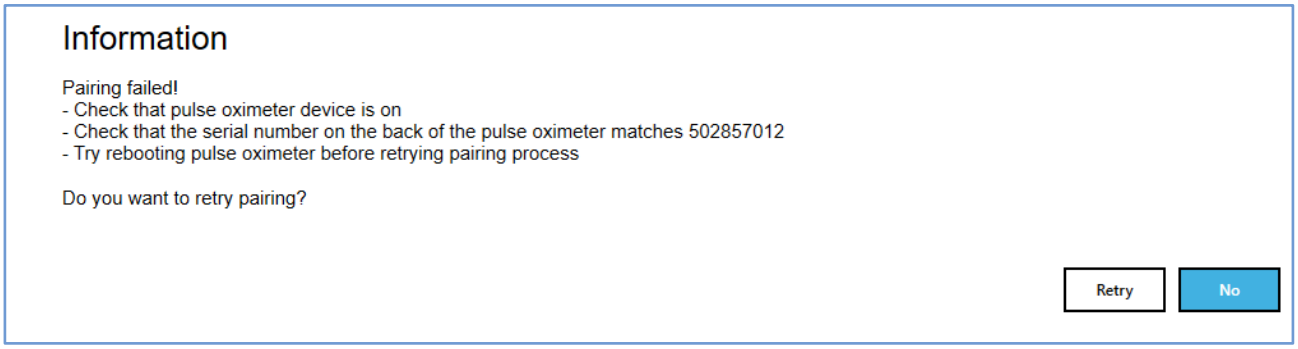
Respiro Device Manager application notifies you if the connecting process was successful. If it was not successful, try again and follow the on-screen instructions. See image below. Note that it is also possible that the pulse oximeter is already connected with another Respiro device, and this is why the connecting process fails. In this case enter the oximeter's serial number in the Pulse oximeter device name field in the Respiro Device Manager main view and click Save. This replaces the old device pair with this new one.

TIP	If the registration is scheduled the above instructions do not apply. In this case the scheduled registration must be first removed using the Respiro Device Manager.

TIP	Pulse oximeter may contain information of two Respiros and the connection is formed with the Respiro that starts first or with the one that is already on. If it is required that the second Respiro's information should be removed the pulse oximeter's serial number must be manually removed from the memory of the Respiro in question using Respiro Device Manager.

Ensure that Nonin pulse oximeter is not already connected to another device by following the pulse oximeter's Bluetooth indicator light (see Nonin Pulse Oximeter Operator's Manual). If the pulse oximeter is connected to another Respiro, find this Respiro and turn it off. Make also sure that the other Respiro which is connected to the same pulse oximeter does not have a scheduled recording set. This keeps the Bluetooth connection active even if the Respiro in question appears to be turned off.

Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function.



4.6.5 HSAT recording mode

In HSAT recording mode the recording is saved directly to Respiro's internal memory. After the recording in HSAT recording mode, Bittium Respiro™ is returned to clinic / hospital and the device is connected to PC with USB cable and the recording data is uploaded locally from the device's internal memory card and stored to the Bittium MedicalSuite™ service platform.

Scheduled recording

In HSAT recording it is possible to set the recording to start and stop at a predefined time in cases where the patient may not be able to start it by himself/herself. The function is activated in the Respiro Device Manager main screen. See chapter 4.6.4, step 3 for information on how to start the Respiro Device Manager application.

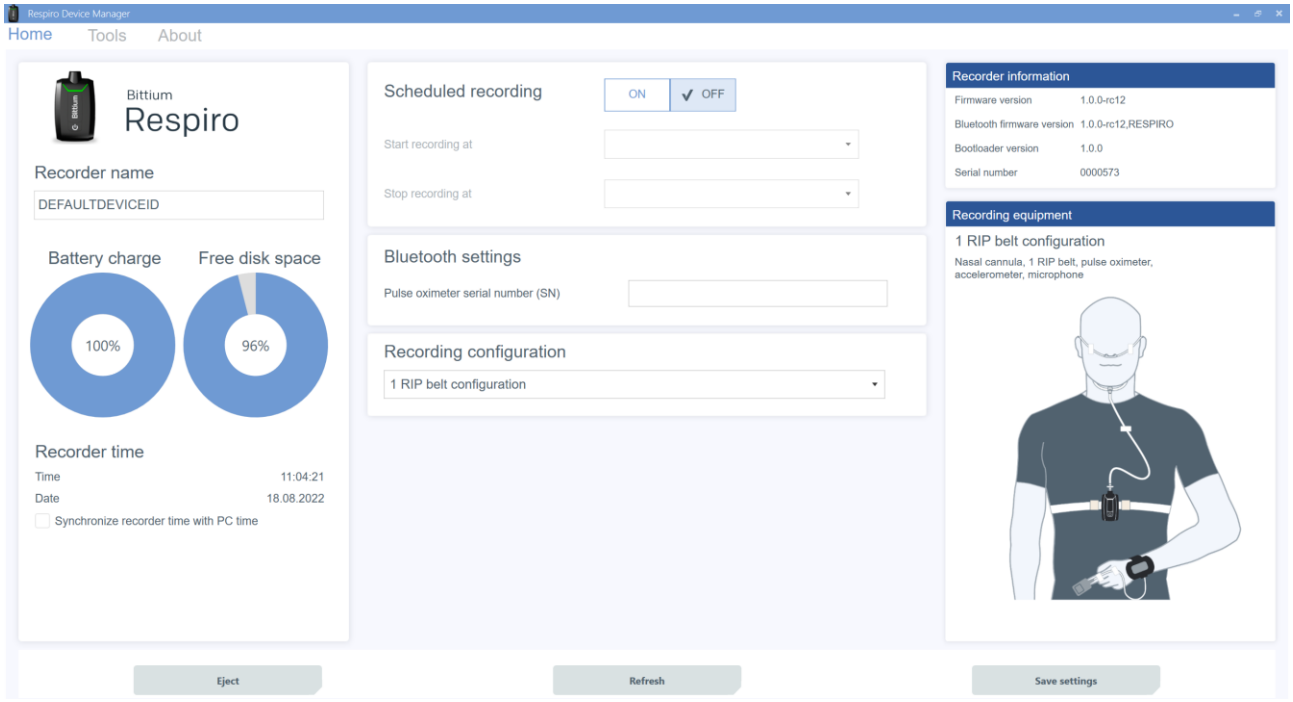
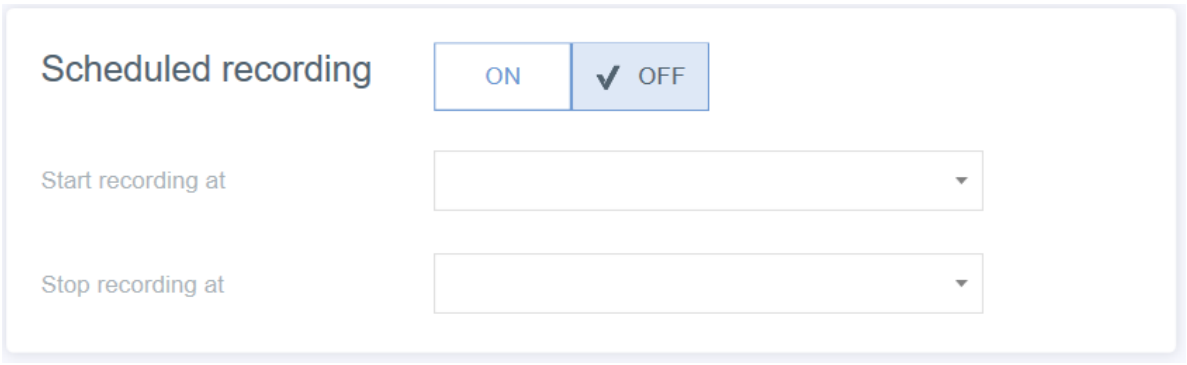


Figure 14 Respiro Device Manager main view



1. Set the Scheduled recording On.
2. Select the starting time from the drop-down list.
3. Select the ending time from the drop-down list.
4. Click Save.

TIP It is recommended to synchronize the device time with the PC time. This can be done in the Respiro Device Manager main view on the lower left-hand side of the view. Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function.

Starting a recording manually

A recording can be started manually by pressing the power button: one short press (<3 seconds) and next press for approx. 8 seconds after which Respiro vibrates once. Recording starts. See also chapter 2.5.2 for corresponding UI indications.

4.7 Recording configuration

Before starting a recording, you must select the configuration that will be used from the drop-down list under Recording configuration. The options are:

- 1 RIP belt configuration
- 2 RIP belts configuration
- 2 RIP belts configuration with ECG

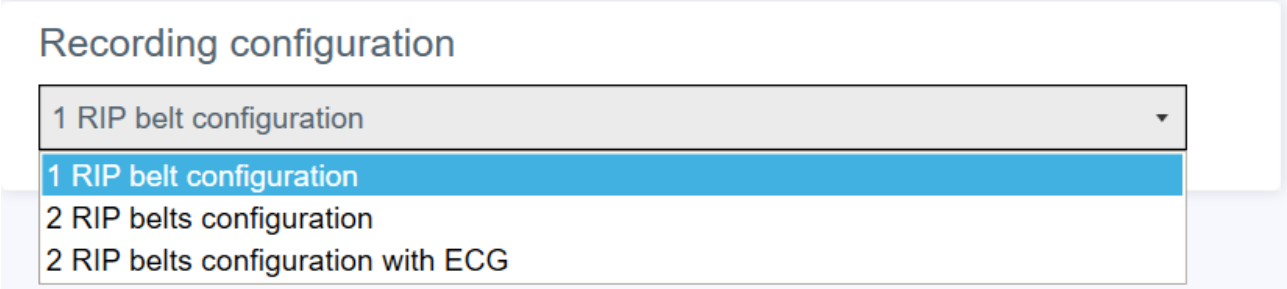


Figure 15 Recording configuration

The selected option is shown in the figure on the right. The selected configuration is valid until it is changed in Device Manager. Click Save after the configuration is selected.

4.8 Starting and ending a recording

See Respiro Quick Guides.

4.9 After the recording

4.9.1 Uploading the recording data after HSAT recording

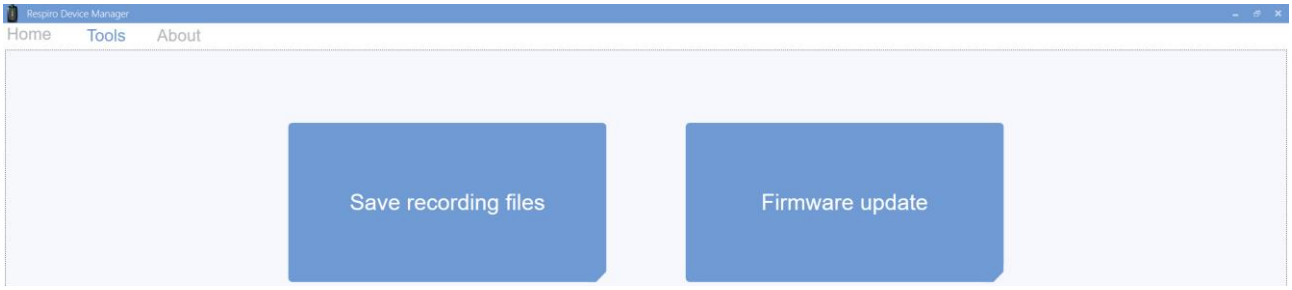
Respiro Device Manager application works in Windows 10 operating system. If a recording state is accidentally on in Respiro device, it is ended automatically when the Respiro device is set in the charging dock.

Follow these instructions to upload the recording data from the Respiro device:

1. Connect the charging dock to a computer with the USB cable.
2. Set the Respiro device in the charging dock. Ensure that the device rests properly in the charging dock.

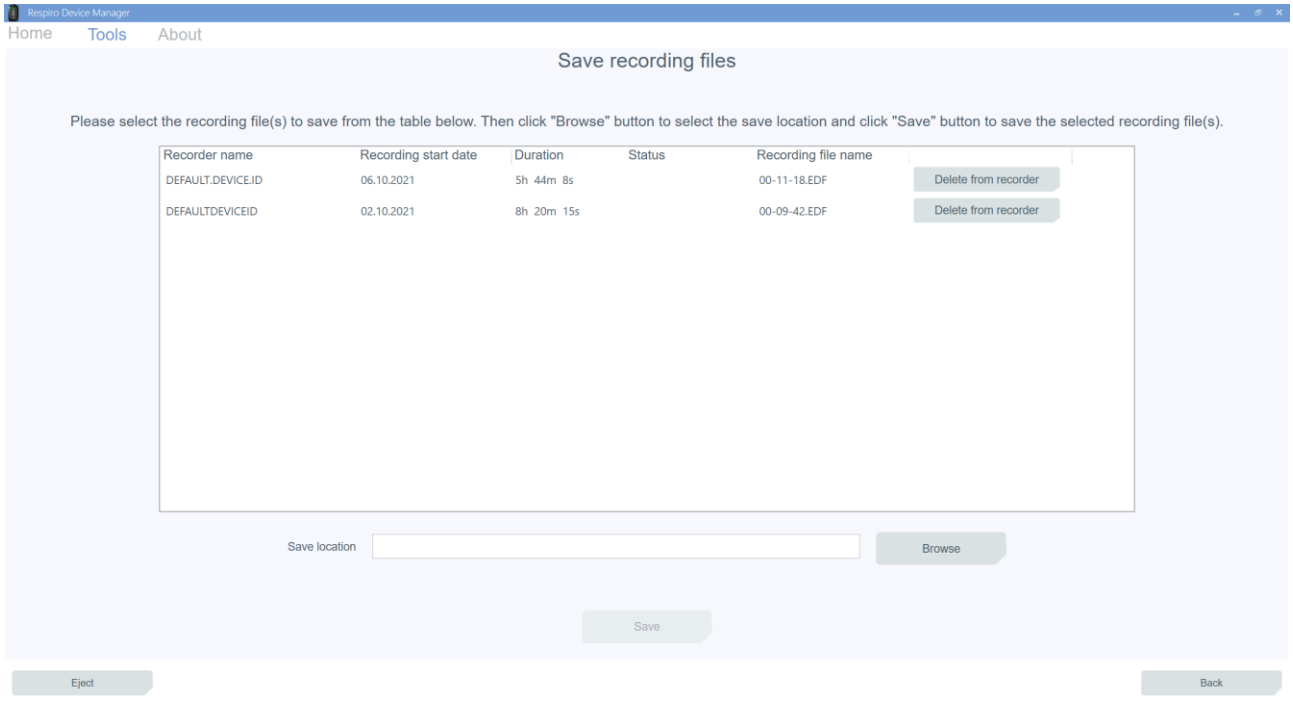
TIP Do not remove Respiro from the charging dock while uploading recording data. Respiro device memory's read function may malfunction and cause an error state that can only be repaired in a service facility.

3. Start Respiro Device Manager application. Wait for the application to detect Respiro. Respiro Device Manager main view opens. See chapter 4.6.4, step 3 for information on how to start the Respiro Device Manager application.
4. Select Tools from the top of the view.
5. Click Save recording files.

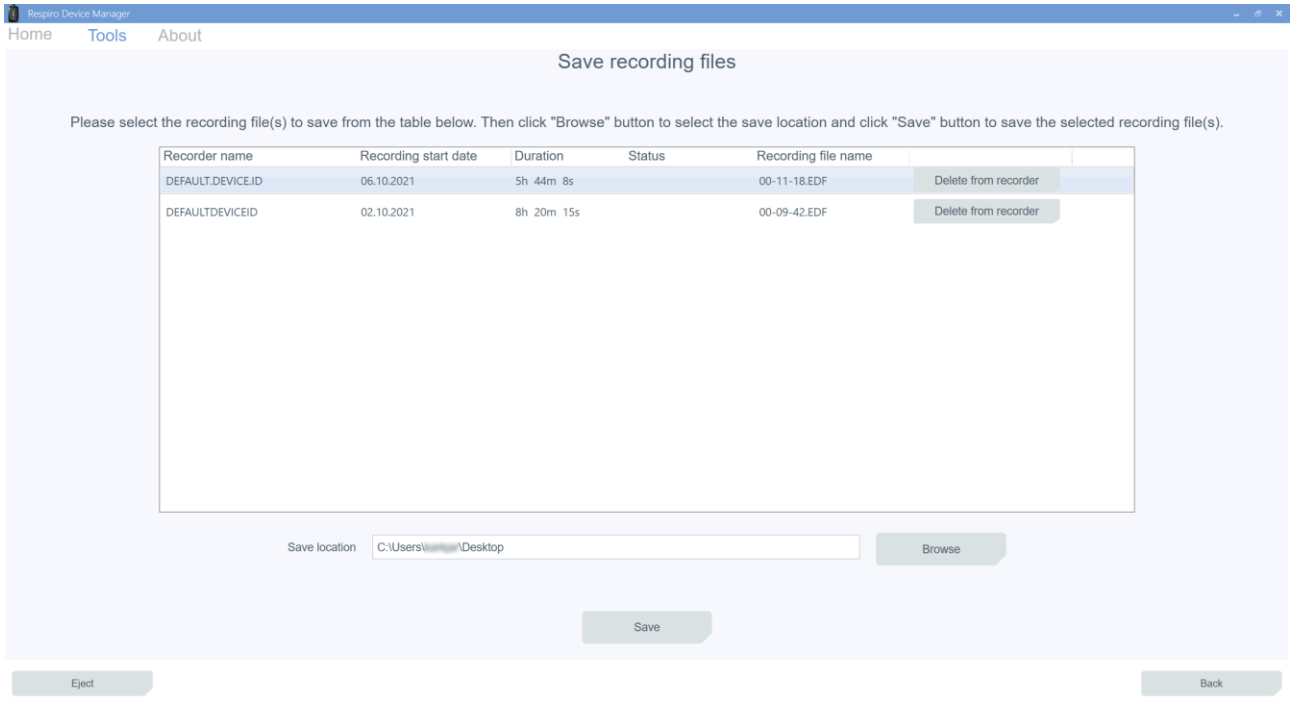


6. Select the uploaded file(s) and click Browse.

TIP You can select several files at the same time by pressing the Ctrl-button during selection.

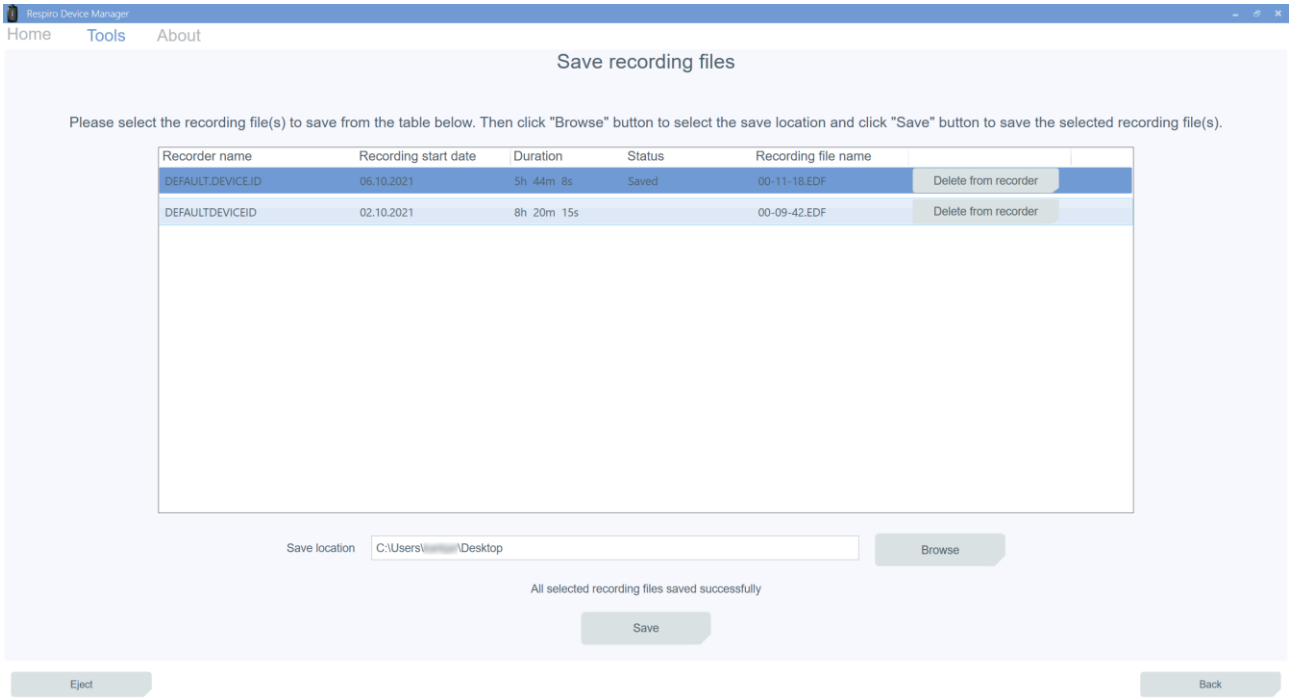


7. Select a save location for the file(s) and click Save.



After the files are saved erase the recording data from the recorder by clicking OK in the Information view.

Those files that were not removed will then remain visible in the Save recording files view.



8. Click Eject. You can remove Respiro from the charging dock when the application instructs you to do so.

TIP If the device contains corrupt files, they will appear with a yellow notification triangle. These unusable files can be deleted from the device in the same way as other files by clicking Delete from device.

4.9.2 Other actions

Remember to erase prior recording data from the Respiro device before preparing it for a new patient. See chapter 4.10.1.

Charge the Respiro and replace the pulse oximeter batteries as required. Different types of batteries (alkaline, lithium, rechargeable) can have an effect on the pulse oximeter's operating time. Jos

When registration is on OR when Respiro is set in the Charger dock, the communication between Respiro and the pulse oximeter is active which also drains the pulse oximeter’s batteries. This is why we recommend to change the pulse oximeter batteries only after Respiro has been prepared for the next patient.

Pack the carry case for the next patient, see Chapter 4.2.

5 MAINTENANCE

You must ensure that the operating system in the computer you are using is up-to-date and secure.

5.1 Cleaning

Respiro, pulse oximeter, wristband, RIP belt(s), Respiro patches, charger, charger dock as well as the carry case, laminated Quick Guide and laminated Notes and Warnings must all be cleaned and disinfected (eg. isopropanol, except for Respiro and pulse oximeter which must be cleaned with mild detergent) before first use and also after every recording. Cannulas, ECG adapter as well as ECG electrodes are disposable. RIP belts can be used more than once with same patient.

Item	Cleaning method	
	Non-fluffing cloth dampened with water and mild detergent.	Non-fluffing cloth dampened with water and isopropanol alcohol
Respiro	X, Avoid wiping the nasal cannula interface with a too wet cloth.	
Pulse oximeter	X	
Respiro patch for 1 RIP belt, patch for 2 RIP belts		X, Check that the patch is intact. The patch can be used in approx. 20 recordings.
Charger		X
Charger dock	X	
Carry case		X
Laminated quick guides and Notes and Warnings		X
The pulse oximeter's wristband is handwashed using a mild detergent in 30 °C water.		

Ensure that the devices and the wristband can dry properly after the cleaning. Use air-drying and do not tumble dry the wristband, for example. Dispose of used nasal cannulas, ECG adapters and ECG electrodes as energy waste.

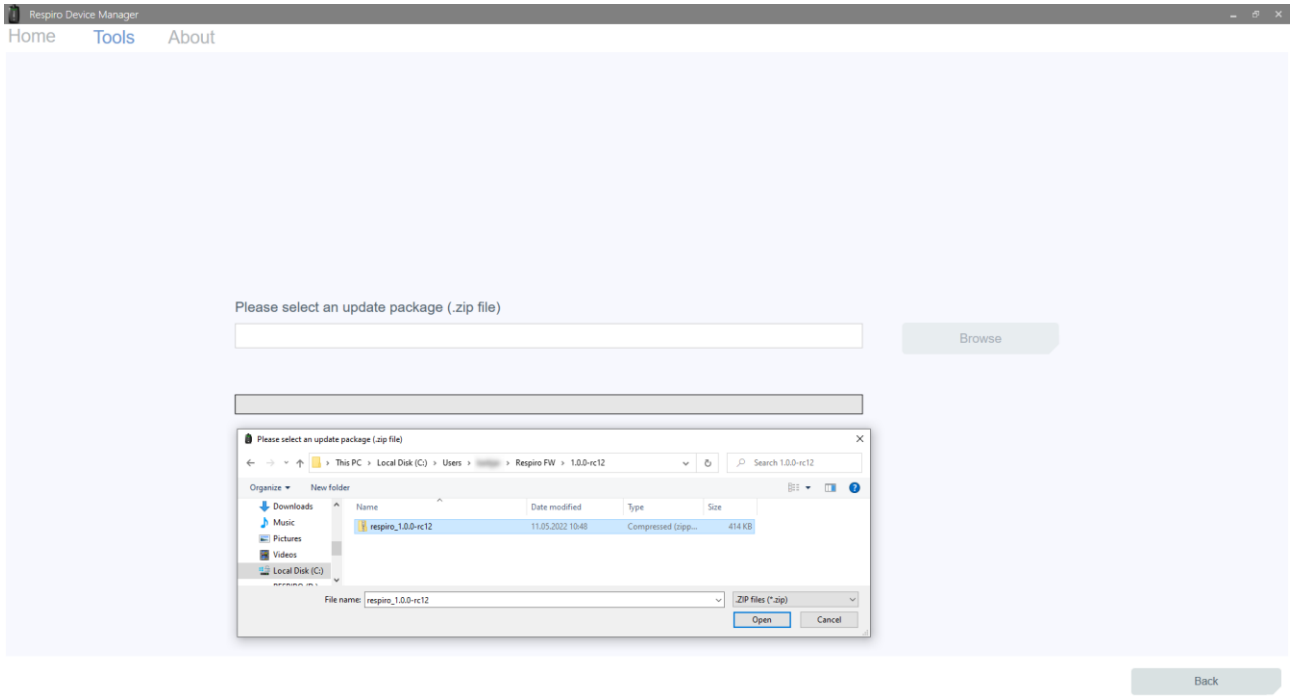
5.2 Changing the Respiro Device Manager language

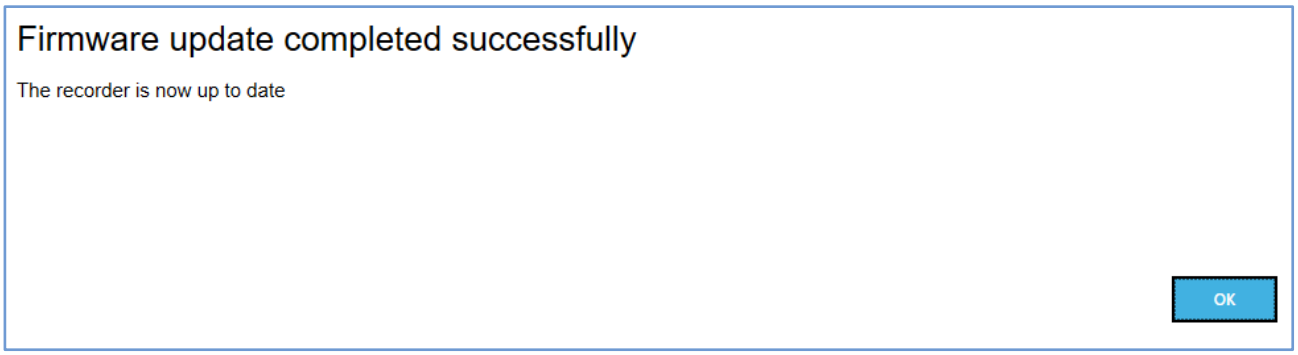
Respiro Device Manager language can be changed by choosing About in the main view. Language options are available via Change language menu.

5.3 Updating Respiro firmware

1. Connect the charging dock to a computer with the USB cable.
2. Set the Respiro device in the charging dock. Ensure that the device rests properly in the charging dock.
3. Start Respiro Device Manager application (see Chapter 4.6.4). Wait for the application to detect the Respiro device. Respiro Device Manager main view opens.
4. Select Tools from the top of the view.
5. Select Update firmware.
6. Locate the update package by clicking the Browse button. Note: The update package is delivered separately, and it must be available on the computer in some pre-defined location.
7. Select the file and click Open.

TIP	Do not remove Respiro from the charging dock while the firmware update is ongoing





8. Firmware update starts after you have selected the update package with the Open button. Respiro Device Manager returns to main view after the update is complete. Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function.

5.4 IT network

- End-user is responsible that device is used according to their organization's IT procedures.
- IT infrastructure shall be designed in a controlled manner with Bittium Biosignals Ltd. Changes to the IT-network could introduce interruption in the data analysis.
- Connection of the system to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks.
    - Subsequent changes to the IT-network could introduce new risks and require additional analysis.
    - Changes to the IT-network include: changes in the IT network configuration, connection of additional items to the IT-network, disconnecting items from the IT-network, update of equipment connected to the IT-network, upgrade of equipment connected to the IT-network.

5.5 Battery replacement

Respiro device battery is an in-built part of the device and can be changed only by Bittium Biosignals Ltd. Battery lifetime depends on device usage modes and recharging cycles. It is recommended to replace the battery after max. 2 years.

When battery replacement is needed, please contact your local distributor or Bittium Biosignals Ltd for battery replacement.

6 TROUBLESHOOTING

Potential issues:

- Respiro does not start recording: Press the power button first <3 seconds until the blue indicator lights are lit blue and then approx. 8 seconds until the device vibrates once to start recording. Make sure that the device is charged.
- Respiro has red light(s) on:
    - If some of the Respiro device's indicator LEDs is red see Tables 5, 6 and 7 below.

Table 5 Respiro common LED indications in error states

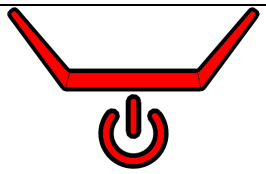
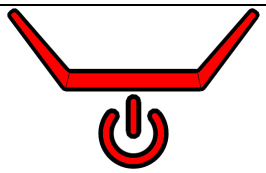
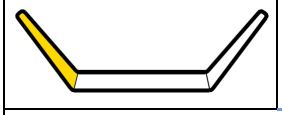
Color	Meaning
	All LEDs flash red once: Failed recording start. Not enough battery charge or device internal memory full. Charge device or free device memory.
	All LEDs and power button LED red: Device internal error. Press power button for 12 seconds and try starting the recording again.
	All LEDs and power button LED red after power button is first pressed for 12 seconds to switch device off and then pressed again twice to start recording: Device requires maintenance.

Table 6 Respiro 3 sensor configuration LED indications in error states

3 sensor configuration (1 or 2 RIP belts), 1 LED on for 1 second cycling from left to right	
	Left LED yellow: Pulse oximeter is connected but finger is not inserted in the sensor. Check connection.
	Left LED red: Pulse oximeter error. Check connection.

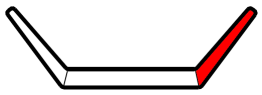
	Center LED red: Nasal cannula error. Check connection.
	Right LED red: RIP belt(s) error. Check RIP belt(s) as well as the connection between Respiro and the patch (press studs).
It is possible to have errors in several sensors simultaneously. Error states are indicated when the equipment is worn on body. If some of the LEDs are green, the sensor in question is ok.	

Table 7 Respiro 4 sensor configuration LED indications in error states

4 sensor configuration (2 RIP belts with ECG), 2 LEDs on for 1 second cycling from left to right	
	Left LED yellow, center green: Pulse oximeter is connected but finger is not inserted in the sensor. Check connection.
	Left LED green, center LED red: Nasal cannula error. Check connection.
	Left LED red, center LED green: Pulse oximeter error. Check connections.
	Left and center LED red: Pulse oximeter and nasal cannula error. Check connections.
	Center LED green, right LED red: RIP belts error. Check RIP belts.
	Center LED red, right LED green: ECG error. Check electrode.

	Center and right LED red: ECG and RIP belts error. Check RIP belts and electrode.

Error states are indicated when the equipment is worn on body and recording is ongoing.
If some of the LEDs are green, the sensor in question is ok.

- Pulse oximeter does not start: Press the pulse oximeter's power button with eg. your fingernail to start it if it does not start automatically. If pulse oximeter still does not start, replace batteries.
- Computer does not detect Respiro when Respiro is in the charging dock and the charging dock is connected to the computer: Check the charging dock connection to the computer and that Respiro is properly set in the charging dock.
- How to connect devices for example after a device failure: See Chapter 4.6.4.
- Respiro LED indicators are dark during charging: Ensure that the charger and the USB connector are properly connected.
- You get the following notification when Respiro is connected to a computer:

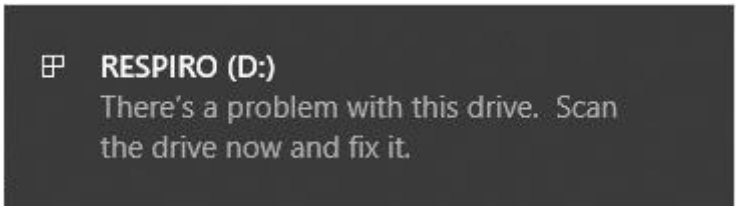


Figure 16 Respiro notification

Click the notification and follow the on-screen instructions. Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function. In Windows the icon can be seen by clicking the ^-icon (Show hidden icons) at the bottom of the display on the right.

7 PRODUCT SAFETY AND REGULATORY INFORMATION

7.1 EU Declaration of Conformity

Certificate of Conformity and Declaration of Conformity in accordance with the applicable directives and standards can be requested from bbs@bittium.com

7.2 EMC

This product meets the requirements of the electromagnetic compatibility (EMC) standard EN 60601-1-2.

8 TECHNICAL INFORMATION

8.1 Respiro dimensions and weight

Height: approx. 81 mm.

Width: approx. 46 mm.

Depth: approx. 19 mm.

Weight: approx. 48 g.

8.2 Device IP classifications

Respiro: IP67

Charging dock: IP31

Pulse oximeter: IP33

8.3 Operating and storage conditions

Table 8 Operating and storage conditions

<table>
<tr><th>Device</th><th>Storage temperature range</th><th>Operating temperature range</th><th>Humidity</th></tr>
<tr><td>Respiro</td><td rowspan="2">- 25… + 70 °C</td><td rowspan="3">+5… + 40 °C</td><td rowspan="3">Operating 15…90 % (non-condensing)

Storage 10…90 % (non-condensing)</td></tr>
<tr><td>Pulse oximeter</td></tr>
<tr><td>Accessories</td><td>+10…+ 30 °C</td></tr>
<tr><td colspan="4">Pressure: 700 hPa-1060 hPa, operating.</td></tr>
<tr><td colspan="4">Battery charging: Battery manufacturers restrict charging the battery above the defined battery temperature limit in order to avoid overheating the battery and to ensure safe user experience in all conditions. As the device manufacturer, Bittium recommends to ensure that Respiro charging environment temperature is max.+30°C to enable smooth and uninterrupted battery charging.</td></tr>
</table>

Always transport the equipment in the carry case. Protect the carry case from snow and rain. Remove the batteries from the pulse oximeter when storing it.

8.4 Respiro specifications

Table 9 Respiro specifications

Respiro		
Nasal pressure	Pressure range	± 7 kPa
	Sampling and storage rate	100 Hz
	ADC conversion	12 bits
Blood oxygen saturation (SpO_2) and pulse rate	SpO_2 range	70 to 100 %
	Pulse rate range	40 to 250 bpm
	Sampling and storage rate (SpO_2)*	1 Hz
	Sampling and storage rate (pulse rate)	1 Hz
Body position and movement	Acceleration range	± 2 g
	Sampling and storage rate	10 Hz
	ADC conversion	12 bits
Respiration effort	Movement range	± 1,5 mm
	Sampling and storage rate	100 Hz
	ADC conversion	10 bits
Mode of operation	Continuous	
Wireless transmisson and reception	Bluetooth Low Energy (BLE)	
* Pulse oximeter's PPG sampling rate is 75 Hz. SpO2 value is calculated based on PPG signal once per second (1Hz). This is a reasonable sampling rate due to the nature of the particular biosignal (slowly variable parameter)		

8.5 Electromagnetic emissions

Table 10 Electromagnetic emissions

Manufacturer's declaration - Electromagnetic emissions		
Respiro is suitable for use in an electromagnetic environment as described below. The users should ensure that the device is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR11	Group 1	Respiro uses RF energy exclusively for its internal function. Thus, the RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

8.6 Immunity test levels

Table 11 Immunity test levels

Phenomenon	Basic EMC standard or test method	Immunity test level Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM, 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table on next page.
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields	EC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between

		0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycle
Surges, Line-to-line	IEC 61000-4-5	± 0,5kV, ±1kV
Surges, Line-to-ground	IEC 61000-4-5	± 0,5kV, ±1kV, 2kV
Electrical fast transients / bursts	IEC 61000-4-4	± 2kV 100kHz repetition frequency

Table 12 Immunity test levels, continued

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,	Pulse modulation 18 Hz	2	0,3	28
870						
930						

		LTE Band 5				
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

APPENDIX 1: SETTING THE DEVICE PASSWORD

Follow these instructions to set a device password for Respiro. It is not mandatory to set this password, so use this function only if it is absolutely required.

Note that the password is device-specific, so keep track of these passwords!

Before you start: Copy the Respiro Device Manager folder eg. to your desktop. After the password is set Respiro Device Manager can only be started from this folder.

1. Put Respiro in the Charging Dock and connect the Charging Dock to your computer.
2. Open Windows File Explorer and select the RESPIRO device drive.
3. Double-click SYS folder.
4. Open DEVICE.CFG file with eg. Notepad++
5. Add line"disk_password":"password_here", after eg. line "spo2_serial":
6. Enter a password in the password_here -part between the “-characters:"disk_password":"password_here",
   You can use any of these characters for a password max. 16 characters in length:
   ! " # $ % & ' ( ) * + , - . / 0 1 2 3 4 5 6 7 8 9 : ; < = > ? @ A B C D E F G H I J K L M N O P Q R S T U V W X Y Z [\ ] ^ _ ` a b c d e f g h i j k l m n o p q r s t u v w x y z { | } ~
   Example string below with password set as 123456:

```
{

"sys_config":{

    "configuration":2,

    "device_id":"DEFAULT_DEVICE_ID",

    "spo2_serial":"123456789",

    "disk_password":"123456",

    "vbat_recorded":1

    }

}
```

7. Save the changes by pressing Ctrl+S.
8. Close the DEVICE.CFG file.
9. Eject Respiro by using the Safely Remove Hardware and Eject Media-function.
   Note that after the password is set Respiro must be powered off and restarted to make the change effective (12 second press to power off device).
   a) Remove Respiro from the charging dock.
   b) Power off Respiro by pressing the button for minimum 12 seconds.
   c) Put Respiro back in the charging dock to verify that password is active. Note that Respiro is no longer visible via File Explorer after the password is set. Start Respiro Device Manager from eg. the desktop where the Respiro Device Manager folder was copied before the password was set.

TIP if you forget the password the device must be sent to maintenance to unlock it!

MANUFACTURER AND EU-IMPORTER FOR NONIN 3150

MDR marketing authorization holder in Europe and manufactured for:

Bittium Respiro™ comply with the requirements of the Medical Device Regulation 2017/745.

Bittium Biosignals Ltd.

Pioneerinkatu 6

70800 Kuopio

Finland

Tel.: +358 40 344 2000

Email: bbs@bittium.com

WEBSITE

You can find up-to-date product information, documents, and updates by visiting the Bittium website at www.bittium.com

SALES

Please contact your sales representative for any questions that you may have about Bittium products.

Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland

Tel.: +358 40 344 2000
Email: bbs@bittium.com
Web: https://www.bittium.com

SERVICE DESK

If you encounter any issues with Bittium medical products, please contact our technical support at

medical.support@bittium.com